

Attorney Docket No.: **BERN-0040**  
Inventors: **Bernstein et al.**  
Serial No.: **09/913,697**  
Filing Date: **January 28, 2002**  
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**REMARKS**

At the outset, Applicants thank Examiner George for the courtesy of Interviews conducted on July 9, 2004 and July 26, 2004. Claims 1-6 and 8 are pending in the instant application. Claims 1-6 and 8 have been rejected. Claims 1, 2, 5, 6, and 8 have been amended. New claims 11 through 13 have been added. Support for these amendments is provided in the specification at page 4, line 11 through page 6, line 4. Thus, no new matter is added by these amendments. Reconsideration is respectfully requested in light of these amendments and the following remarks.

**I. Rejection of Claims 1-6 and 8 under 35 U.S.C. § 103(a)**

Claims 1-6 and 8 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Horiuchi et al. (JP 02-229103) in view of Lezday et al. (U.S. 6,096,327).

Applicants respectfully traverse this rejection.

As discussed during the July 9, 2004 interview with the Examiner, on March 12, 2003 Applicants submitted a Rule 131 Declaration providing evidence of conception and reduction of the instant invention prior to the filing date of U.S. Patent 6,096,327. Thus, as acknowledged by the Examiner in the interview of July 26, 2004, U.S. Patent 6,096,327 is not a valid prior art reference with respect to this invention.

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As also acknowledged by the Examiner during the July 26, 2004 interview, JP -2-229103 alone does not render obvious the instant invention as this reference contains no teaching of alpha 1-antitrypsin or serpins with alpha 1-antitrypsin like activity.

Withdrawal of this rejection under 35 U.S.C. § 103(a) is therefore respectfully requested.

## II. Claim Amendments

During the July 9, 2004 interview Applicants requested reconsideration of the necessity of the "in milk" limitation in the claims. Milk was clearly used simply as a vehicle for the alpha 1-antitrypsin and is not required for activity of the instant claimed invention. During the telephone interview of July 26, 2004, the Examiner acknowledged that other vehicles were taught for serpins with alpha 1-antitrypsin like activity and that the limitation of "in milk" was not required for these compositions. However, with respect to alpha 1-antitrypsin, the Examiner maintained that the "in milk" limitation was needed because all experiments with this specific serpin were performed in milk. While Applicants respectfully disagree with the Examiner, in an earnest effort to advance the prosecution of this case, the claims have been amended in accordance with the Examiner's suggestion to remove the unnecessary limitation of "in milk" when referring to serpins with

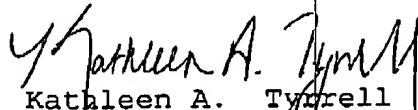
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alpha 1-antitrypsin like activity and to maintain the limitation of "in milk" when referring to compositions comprising alpha 1-antitrypsin. These amendments are clearly supported by teachings at pages 4-6 of the instant specification and are believed to address most clearly the Examiner's concerns.

### III. Conclusion

Applicant believes that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

  
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